

Efficacy of probiotics and selective decontamination of the digestive tract in reducing bacterial translocation in patients with pylorus preserving pancreaticoduodenectomy

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/01/2009	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M A Boermeester

Contact details
Academic Medical Centre
Departement of Surgery
G4-109.2
P.O. Box 226600
Amsterdam
Netherlands
1100 DD
m.a.boermeester@amc.uva.nl

Additional identifiers

Protocol serial number
NTR280

Study information

Scientific Title

Acronym

SDD-PRO-Whipple Study

Study objectives

Peri-operative administration of probiotics or selective decontamination of the digestive tract (SDD) has an effect on small bowel bacterial overgrowth and bacterial translocation to lymph nodes in patients undergoing pylorus preserving pancreaticoduodenectomy (PPPD) by protecting or enhancing bowel (mucosa) permeability.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local ethics committee

Primary study design

Interventional

Study design

Multicentre randomised single-blind active controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bacterial translocation in pancreaticoduodenectomy

Interventions

After informed consent, patients will be randomly assigned to three groups:

Group A (n = 10): probiotics

Group B (n = 10): selective decontamination of the digestive tract (SDD)

Group C (n = 10): standard treatment

All patients will receive standardised anaesthesia and post-operative analgesia. The effect of pre-operative prophylaxis regimes can be assessed by bacterial counts in a small jejunal biopsy and an adjacent lymph nodes. Also the effect of the prophylactic regimes on gut permeability, cytokine production and faecal flora will be assessed.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Intestinal permeability and bacterial translocation following major pancreaticobiliary surgery.

Key secondary outcome(s)

1. Effect of probiotics compared to control treatment on intestinal permeability after major pancreaticobiliary surgery
2. Effect of probiotics compared to control treatment on bacterial translocation to bowel wall and mesenteric lymph nodes
3. Comparison of probiotics to SDD on parameters of intestinal permeability and bacterial translocation
4. Determination of intestinal bacterial overgrowth after probiotics or SDD peri-operative treatment versus control treatment
5. Determination of systemic and local inflammatory response due to bacterial translocation after probiotics or SDD

Completion date

01/02/2006

Eligibility

Key inclusion criteria

1. Aged greater than 18 years, either sex
2. Patients planned for pylorus preserving pancreaticoduodenectomy for suspected malignant or premalignant disease
3. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Antibiotics within a week prior to surgery (peri-operative antibiotics are allowed)
2. Use of other probiotic products 4 weeks before or during the study
3. Non-resectable cancer of the pancreas

Date of first enrolment

01/04/2005

Date of final enrolment

01/02/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Winclove BioIndustries BV (Netherlands)

ROR

<https://ror.org/02c0pn910>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration